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Glossary of terms used for assessment of scientific data related to an exposure claim

Numerical change:
Any numerical difference (increase or decrease) of a data point relative to a specified reference.

Statistically significant change:
Any numerical change (increase or decrease) of a data point relative to a specified reference that shows statistical significance in a scientifically valid and specified statistical test.

Significant change:
Not to be used in order to prevent ambiguity with regard to 'statistical significant change'.

Substantial change:

- In the context of 'substantial reduction of exposure or risk' 'substantial' is used as defined in IOM Principle 4, i.e. when the change can be anticipated to result in a change of morbidity or mortality.
- In the context of any other change (increase or decrease) of a data point relative to a specified reference 'substantial' is used when the change is statistically significant and >= 50% of the reference value.

Biologically relevant change:
Any numerical change (increase or decrease) of a data set in non-clinical studies relative to a specified reference that shows statistical significance in a scientifically valid and specified statistical test that is judged by an expert or a group of experts as having biological relevance taking the variations of the analytical procedures and the physiological variation of the biological test system(s) into account. Biologically relevant changes are distinguished from physiological changes such as fluctuations of blood glucose concentrations that may be statistically significant but have no biological meaning in a toxicological assessment. Biological relevance is therefore an expert judgment. We attempt to characterize what determines a biologically or clinically relevant change for defined endpoints by means of documented expert criteria.

Toxicologically relevant change:
Any numerical change (increase or decrease) of a data set representing an adverse effect or being a surrogate indicator of a clinically relevant change in non-clinical studies relative to a specified reference that shows statistical significance in a scientifically valid and specified statistical test and that is judged by an expert or a group of experts as having toxicological relevance taking the variations of the analytical procedures and the physiological variation of the biological test system(s) into account.

Source: https://www.industrydocuments.ucsf.edu/docs/mfhk0001

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Clinically relevant change:
Any numerical change (increase or decrease) of a data set relative to a specified reference that shows statistical significance in a scientifically valid and specified statistical test and that is judged by an expert or a group of experts as having clinical relevance taking the variations of the analytical procedures and the physiological variation of the biological test system(s) and subjects into account. Clinical relevance is therefore a medical expert judgment.

Change:
Not to be used in order to prevent ambiguity with regard to any of the term defined above.

Source: https://www.industrydocuments.ucsf.edu/docs/mfhk0001